DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2015

Covidien
Ms. Mary Mellows
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K142656
Trade/Device Name: Absorbable Surgical Gut Suture
Regulation Number: 21 CFR 878.4830
Regulation Name: Absorbable surgical gut suture
Regulatory Class: Class II
Product Code: GAL
Dated: December 23, 2014
Received: December 30, 2014

Dear Ms. Mellows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142656

Device Name
Absorbable Surgical Gut Suture

Indications for Use *(Describe)*
Plain, Chromic and Mild Chromic gut absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in microsurgery, cardiovascular or neurological surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) summary information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 (203) 492-5284 (T)
CONTACT PERSON:	Mary Mellows Senior Specialist, Regulatory Affairs
DATE PREPARED:	September 17, 2014
TRADE/PROPRIETRY NAME:	Surgical Gut Suture
COMMON/USUAL NAME:	Absorbable Surgical Gut Suture
CLASSIFICATION NAME:	Suture, Absorbable, Natural
FDA PANEL NUMBER:	79
PRODUCT CODE:	GAL
CLASS CODE:	Pursuant to 21 CFR 878.4830, absorbable surgical gut suture is a Class II device
LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCY IS CLAIMED:	Surgical Gut Suture (K885018)

REASON FOR 510(K) SUBMISSION: Obtain clearance for Covidien's surgical gut suture (plain, mild, and chromic) with a manufacturing process modification to include an additional sodium hydroxide (1N NaOH) bath or soaking step to inactivate any potential viruses. In addition, the Contraindications and Warning sections of the Instructions for Use are being modified to make them clearer for the user.

DEVICE DESCRIPTION: Covidien's surgical gut sutures are absorbable sterile surgical sutures composed of purified connective tissue (mostly collagen) derived from the serosal layer of bovine intestines. They are packaged in a solution of 87% isopropanol, 12% water and 1% triethanolamine.

INTENDED USE: Plain, Chromic and Mild Chromic gut absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in microsurgery, cardiovascular or neurological surgery.

TECHNICAL CHARACTERISTICS: The proposed surgical gut suture is substantially equivalent and its fundamental scientific technology has not been altered as compared to the predicate devices.

MATERIALS: All components of the surgical gut suture are similar to the predicate surgical gut suture. All materials are similar and have been tested in accordance with ISO Standard 10993-1.

PERFORMANCE DATA: Design verification and pre-clinical validation studies were conducted to demonstrate that the proposed surgical gut sutures are safe and effective and perform as intended. In vitro and in vivo testing to support the intended use of this device includes:

- In Vitro
  - Visual/Tactile
  - Suture Removal
  - Diameter
  - Knot Pull
  - Needle Attachment
- In Vivo
  - Strength Loss
  - Mass Loss
- Biocompatibility

CONCLUSION: The result of these tests demonstrates that the proposed surgical gut sutures are substantially equivalent to the predicate device and does not introduce additional risk to the patient.